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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.	Applicant(s)
09/126,945	Libermann et al.
Examiner	**Group Art Unit**
Scott D. Priebe, Ph.D.	1632

THE PERIOD FOR RESPONSE: [check only a) or b)]

a) X expires 3 months from the mailing date of the final rejection.

b) ☐ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on _____ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on Nov 7, 2000 has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:

X The proposed amendment(s):

☐ will be entered upon filing of a Notice of Appeal and an Appeal Brief.

X will not be entered because:

X they raise new issues that would require further consideration and/or search. (See note below).

X they raise the issue of new matter. (See note below).

☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

X they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: *Proposed claims 24, 51, 105, 107, 109 & 111 raise new issues under 35 USC 112, 1st & 2nd para. - proteins do not "generate" antibodies. (continued below)*

☐ Applicant's response has overcome the following rejection(s):

☐ Newly proposed or amended claims _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

X The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see attachment

☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

X For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: *84-100*

Claims objected to: *27, 30, 33, 36, 39, 54, 57, 60, 63, 66, 110, and 112*

Claims rejected: *24-26, 28, 29, 31, 32, 34, 35, 37, 38, 40-53, 55, 56, 58, 59, 61, 62, 64, 65, 67-83, 105-109, 111,*

☐ The proposed drawing correction filed on _____ ☐ has ☐ has not been approved by the Examiner.

☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ .

X Other *Proposed claims 149-155 introduce new matter for "regulatory elements capable of directing translation". Proposed claim 154 raises new issue under 35 USC 112, 1st and 2nd para., there is no nexus for "a polypeptide" in line 2 to any other element. Proposed claim 128 would require new search and consideration.*

SCOTT D. PRIEBE, PH.D.
PRIMARY EXAMINER
ART UNIT 1632

Attachment to Advisory Action

Applicant's request for reconsideration of the finality of the rejection of the last Office action is not persuasive. The alleged new grounds of rejection appearing at pages 7-8 in the final Office action (Paper No. 19, 8/7/00) are a rebuttal to Applicant's arguments addressed to the original grounds of rejection as set forth on pages 7-8 of the Office action of 3/16/00 (Paper No. 11). Thus, this rebuttal is not a new grounds of rejection.

Proposed claims 43, 67, 76, 113, 122 and 129 would overcome the rejection under 35 USC 112, 2nd para. Proposed claim 75 would overcome the rejection of claims 75-83 under 35 USC 112, 1st para.

With respect to the rejection of claims 137-148 under 35 USC 112, 1st para., Applicant's argument reiterates what was stated in the rejection. The specification describes fusion polypeptides, whereas the claims are far broader since they do not restrict the "nucleotide sequence heterologous to SEQ ID NO: 1" to a nucleotide sequence to one that encodes an amino acid sequence in frame with a recited part of SEQ ID NO: 2 to yield a fusion polypeptide as originally described.

With respect to the rejection of claims 24-26, 28, 29, 31, 32, 34, 35, 37, 38, 40, 41, 43-53, 55, 56, 58, 59, 61, 62, 64, 65, 67-74, 105, 107, 109, 111, and 113-120 under 35 U.S.C. 112, first paragraph, the proposed amendment does not overcome the rejection for the reasons of record regarding making polynucleotides encoding polypeptides to be used for making antibodies that the specification teaches how to use. Mere recitation of the function of antibody binding does

not correct the deficiencies in the specification for making the embodiments without undue experimentation. The present situation is not sufficiently similar to that in *In re Angstadt* where numerous working examples of operative embodiments were disclosed, and the question was whether the specification needed to provide guidance for every working embodiment. In contrast, the instant provides a single amino acid sequence (SEQ ID NO: 2) which could reasonably be expected to be successful for making antibodies selective for SEQ ID NO: 2, and provides limited guidance teaching specific epitopes that might be expected to be particularly antigenic. However, the claims in reciting 90-95% identity embrace, for all practical purposes, an infinite number of potential embodiments with the specification providing very limited guidance on which of these would be operative for making the desired antibodies, i.e. those that bind SEQ ID NO: 2. With respect to the utility of antibodies that bind polypeptides that differ in sequence from SEQ ID NO: 2, yet retain its function, the specification fails to enable how to make such embodiments for the reasons of record. It is acknowledged that the need for routine experimentation is permissible. However, Applicant has provided no evidence that those skilled in the art routinely engage in the type of experimentation required to identify the operative embodiments embraced by the proposed claims; for example, intentionally altering the amino acid sequence for a natural protein in order to obtain functional variants of that protein (most of which would not exist in nature), or in order to make antibodies that recognize the natural protein. What is routine in the art is to use a native protein, such as the protein of SEQ ID NO: 2, to make antibodies that recognize the native protein.